PHARMACEUTICS-I- BP103T

UNIT: 3 (Monophasic liquids, Biphasic liquids)

CLASS:1

TOPIC: Monophasic liquids

. INTRODUCTION

• A solution is a liquid-preparation that contains one or more soluble chemical substances dissolved in a specified solvent.

• One phase system

Gargles - They are aqueous solutions used in the prevention or treatment of throat infections. Usually, they are prepared in a concentrated solution with directions for the patient to dilute with warm water before use. - They brought in intimate contact with mucous membrane of throat and allowed to remain in contact with it for few seconds before thrown out of the mouth - Container-clear, glass bottles with plastic screw cap. Colored bottles are required to be used if protection is required. - Labelling- 'for external use only" and proper dilution instruction should be written on label - Method of preparations- They are usually prepared by dissolving all ingredients in solvents and then make up the volume as required.

Advantages-

1. Easy to use for the treatment of infection of pharynx just by gargling the solution using air from the lungs

2. Relieve Soreness In Mild Throat Infection

3. Supplied in conc. For so reduce container size 4. Suitable for variety of drugs like antibiotic, antiseptic etc

Disadvantages

1. Temporary effect of drugs

2. Not suitable for patients having respiratory problems

3. They might be swallowed

Formulation component of gargles

cosolvent: glycerine, propylene glycol etc used to enhance solubility of drug.

Vehicle: Water, sometimes alcohol. To dissolve the excipients

Colouring agent: Amaranth, tartrazine solution or any FDA approved colour etc Attractiveness

Flavouring agent: cardamom oils, cinnamon oils, menthols. To enhance acceptability

Preservatives: Phenol, Choro cresol, Benzoic acid and its salts. To inhibit the growth of microorganism. Medicament:

1. phenol,thymol- Anti-infective
2. potassium chlorate- Astringent
3. volatile oil- Antiseptic and deodorants
4. potassium permanganate- Bactericidal.

Antioxidant: Ascorbic acid, Sodium bisulfite, Sodium metabisulfite, thiourea to prevent oxidative degradation of drugs.

Mouthwashes

• These are non-sterile aqueous solution with pleasant taste and odour used for oral hygiene (clean and deodorize buccal cavity) and to treat infections of the mouth.

• Container-white flutted bottles

• Labelling-proper directions for mouthwash dilution must be mentioned

• "for external use only"provided in pH RANGE OF 5 TO 9.5

• "Not to be swallowed in large amount"

Advantages-

1. Utilized to remove Loosen debris and food from the mouth
2. Provide deodorant, refreshning, local analgesics or astringent effects
3. Sometimes used to treat the mouth infection by using antibacterial agent.

Disadvantage- If pH not monitored properly then may damage mouth tissues.

Classifications of mouthwashes

• Mouthwashes (mouthrinses) are generally classified as – 1. cosmetic or 2. therapeutic or 3. Combination of the two.

1. Cosmetic rinses are commercial products that remove oral debris before or after brushing, temporary suppress bad breath, diminish bacteria in the mouth and refresh the mouth with a pleasant taste.

2. Therapeutic rinses ALONG WITH benefits of their cosmetic counterparts, they also contain an added active ingredient, (for example fluoride or chlorhexidine), that help protect against some oral diseases.

Method of preparation-

• Solution method where most of the ingredients are dissolved in solvent or co- solvent mixture to form clear solution.

Deoderant sodium chloride and sodium bicarbonate as a hypertonic solution To deodourize the mouth cavity Sweetening agent sodium saccharin, sorbitol, glycerol, Xylitol improve the taste alcohol The amount of alcohol is usually ranging from 18 - 26 %. preservative and a semi-active ingredient. Abrasives- e.g. calcium carbonate, calcium phosphate, aluminium hydroxide, sodium bocarbonate Abrasives are the substances that are used for abrading, grinding or polishing. They remove substances adhering to the surface of the teeth without scratching it and bring out their natural luster Anti-halistosis agents zinc ion the anaerobic, Gram-negative bacteria use sulphurcontaining amino acids as substrates in their production of volatile sulphur- containing compounds (VSC) which gives unpleasant smell in mouth . This agent stops this

THROAT PAINT

• Viscous liquid preparation Used for mouth and throat infection

• Paints can be applied to skin and mucous membranes. But all paints cannot be used for application onto mucous membrane

• Container-airtight, coloured fluted bottle

• LABELING-'for external use only", it should also contain auxillary label like: Throat paints usually contain volatile oils as flavouring agents. Therfore to prevent their volatalisation at higher temperature,

• NOT TO BE SWALLOWED IN LARGE QUANTITIES KEEP THE CONTAINER TIGHTLY CLOSED.

• Storage-dispensed in air tight container and stored in cool place

• Direction: Throat paints should contain the direction to the patients as, Apply with camel brush, as directed.

Advantages- 1. Used for treatment of throat infection and mouth infection 2. Highly viscous solution so retain to the applied place for longer period of time 3. Glycerine used as a solvent which provides viscosity and turns liquid sweet.

Disadvantages- 1. Applied with the help of brush or small cotton piece 2. They initiate salivation, hence patient has to spit

Formulations- 1. SOLVENT- Viscous solvent must be used so as to retain the formulation at the site of action for longer time e.g. glycerin, liquid paraffine 2. Medicament- Antiseptic-e.g Iodine, crystal violet Astringent-tannic acid, boric acid Anti-infective-phenol, thymol 3.Flavoring agent-They get rid of the unpleasant smell and taste of the other raw materials and give a cold, refreshing taste. E.g.water-insoluble essential oils, such as spearmint, peppermint, eucalyptus and menthol are often used as flavouring agent dissolved with the help of cosolvents 4.. Colouring agent- an attractive appearance e.g. FD&C Colours 5. Sweetening agent- improve the taste e.g. sodium saccharin, sorbitol, glycerol, Xylitol 6. Preservatives- prevent the growth of micro-organisms in mouthwashes. E.g. sodium benzoate, methyl paraben and ethyl paraben

Method of preparation • Simple solution method with the aid of heat

Syrup - It is a concentrated aqueous solution of a sugar, usually sucrose with or without medicinal and flavoring agent. - Flavored syrups are a convenient form of masking disagreeable tastes.

- Advantages- 1. Act as, antioxidant by retarding the oxidation, as sugar is hydrolyzed in to laevulose and dextrose. 2. Act as preservative by retarding the growth of bacteria, fungi and mould because of high osmotic pressure. 3. Good patient compliance especially pediatric patients as syrups are sweet in test. 4. Pleasant means of administrating liquid dosage form of a disagreeable taste 5. Much like by children and adults 6. Suitable for water soluble drugs.

Disadvantages of syrup 1. Not suitable for diabetic patients 2. Children may mistakenly taken extra dose as pleasant taste 3. Concentration if not appropriate result in microbial growth 4. If kept in cold place , sucrose crystallizes and is warm place occur fermentation.

Types of syrup

1. simple syrup- when water is used alone for the preparation of sucrose solution. E.g. simple syrup IP. Consist of 66.7 % w/w of sucrose in water

2. medicated syrups-when syrup contains medicinal substances used for therapeutic purpose E.g. codeine phosphate syrup,ferrous sulphate syrup

3. Flavoured syrups-when syrup contains aromatic or flavouring agents E.g. orange syrup, lemon syrup

Formulation component of syrup:

Sucrose or other sugar substituent Sweetener, vehicle: Water, glycerin. As a solvent for dissolving ingredients. Chemical stabilizers: Glycerin, sorbital, propylene glycol. To prevent crystallization of sucrose. Colouring agent: Amaranth, tartrazine solution etc Attractiveness. Flavouring agent: Raspberry juice, lemon juice, vanilla flavour etc. To enhance acceptability. Preservatives: Benzoic acid, sodium benzoate, methyl paraben. To inhibit the growth of microorganism. Medicament: Lincomycin- Analgesic, Meperidine Hydrochloride-antiemetic, Chhlorpromazine HCL-Antibiotic

Method of preparations

Three methods- 1. Solution with the aid of heat-sugar is added to purified water and heat is applied until solution forms. Then solution allowed to cool and volume is adjusted.

2. Solution with agitation-sugar and ingredients are dissolved in purified water by placing in container and allowed to agitate the mixture for long time till whole of the sugar dissolves and then make up the volume

3. Percolation method-sucrose is percolated with purified water as solvent by slowly passing the solvent through column of crystallization of sucrose to dissolve it. The percolate is collected. This process is repeated until the whole sugars dissolves.

DISPENSING-in well dried, well stoppered bottles, narrow mouthed, amber coloured bottles with plastic screw cap • Storage-store in cool place • Label-store in fairly cool temperature, not exceeding 25°C in dark place.

ELIXIRS

Elixirs as clear, sweetened hydroalcohol liquids intended for oral use containing flavoring substances or active medicinal agents. Their primary solvents are alcohol and water, with glycerin, sorbitol and syrup sometimes as an additional solvent and/or sweetening agents. Alcohol concentration 4-40%

Advantages of presence of alcohol 1. Enhances the solubility of insoluble drugs in water 2. If more than 20 % alcohol present, no requirement of preservative as alcohol acts as a preservative

Types of elixir

1. non-medicated elixir- do not contain medicament, but contain flavoured substances to make it acceptable

2. medicated elixir-when elixir contains medicinal substances used for therapeutic purpose like antibiotic, antihistaminics, antitussive etc E.g. piperazine citrate elixir, paracetamol elixir

Formulation component of elixir:

vehicle: Water, glycerin, alcohol. As a solvent for dissolving ingredients. Colouring agent: Amaranth, tartrazine solution etc. Attractiveness. Flavouring agent: Raspberry juice, lemon juice, vanilla flavour, orange oil, tincture of lemon etc. To enhance acceptability of the product. Preservatives: Benzoic acid, sodium benzoate, methyl paraben, chloroform spirit, methyl ester of p- hydroxy benzoic acid. To inhibit the growth of microorganism. Medicament: Antibiotic, antihistaminics, sedative Therapeutic purpose. Sweetening agent: Sucrose, saccharine, syrups, glycerine To enhance the taste. Stabilizer: EDTA, Citric acid. To stabilize the product byminimize the darkening that occurs on storage. Disodium edetate should be used to sequester heavy metals that catalyse decomposition of the antibiotics.

Method of preparation:

• Dissolve the water-soluble ingredients in part of the water, add and dissolve the sucrose in it. • Dissolve the other ingredients in the alcohol.(Concentration of alcohol should be 5- 40% to make clear solution) • The aqueous solution is then added to the alcoholic solution with constant stirring and make up the volume with the solvent or vehicle specified in the formulation. Elixirs should be brilliantly clear and therefore strained or Filtered, if necessary • A high alcoholic content is maintained during preparation by adding aqueous phase to the alcoholic solution.

Storage It should be dispensed in narrow mouthed, screw capped, colorless plain bottle. In cool place , to prevent volatilization of alcohol at high temperature Advantages over syrups less sweet than syrups • Elixirs are more fluid than syrups. • It often is desirable, it is more effective in masking such tastes. • More stable than syrups • Elixirs are more readily prepared and manufactured than syrups. • An Elixir may contain both water and alcohol soluble ingredients.

Disadvantage of elixirs • Alcohol is not good for children. • Because they contain volatile materials, it must be stored in a watertight screw-top jar and away from sources of ignition. Label- All necessary requirements of liquid dosage form meant for internal use. Amount of alcohol content must be mentioned

Eardrops

Solutions of drugs intended to be instilled into the ear with a dropper.

• Container- coloured , fluted glass bottle with dropper in the cap • Labelling- ‘FOR EXTERNAL USE ONLY’ • Storage-’store in cool place’

Advantages- 1. Use for the removal of ear wax 2. Used in treatment of ear infection, inflammation and pain

Disadvantages- 1. Due to liquid nature, patient has to tilt the head at 45◦C For about 10-15 minutes 2. Aqueous solutions are not suitable as they donot get mixed with fatty serum

FORMULATIONS

1. Solvent-Unhydrous Glycerine and propylene glycol used mainly for two purpose- A. To soften the ear wax As they are miscible with fatty ear wax and make maximum contact between medication and ear tissue. B. Hygroscopicity of vehicle draw moisture from tissue thus reduce inflammation and prevent growth of microorganism 2.Preservative- to prevent growth of microorganism e.g. chlorbutanol (0.5%), thiomersal (0.01%) 3.Antioxident- to prevent oxidation of active medicament e.g. sodium biosulphate 4. medicament- Antiinfective- chloramphenicol Wax softner-hydrogen peroxide,sodium bicarbonate Antiseptic-phenol, boric acid Astringent-aluminium acetate Anti-inflammatory agent-hydrocartisone,dexamethasone

METHOD OF PREPARATION • SIMPLE SOLUTION METHOD

Nasal drops

• Aqueous solution that are instilled into the nose with dropper • Container- coloured fluted bottles fitted with dropper or in suitable plastic container • Labelling- 'FOR EXTERNAL USE ONLY' • Storage- stored in cool place

Advantages- 1. Used to reduce swelling of the nasal mucosa 2. Used to reduce nasal congestion

Disadvantages- 1. They may induce nasal congestion if not used as per direction given 2. Aqueous solution donot prolong the action

Requirement for nasal vehicle 1. pH Must be between 5.5 to 7.5. 2. Have mild buffer capacity 3. Compatible with nasal tissue 4. Compatible with other active ingredients 5. Must contain preservatives 6. Stable 7. Have a proper viscosity

Formulation ingredients

1. Vehicle- water and preparation must be isotonic 2. preservatives- prevent growth of microorganism in product • E.g. chlorbutanol(0.5%), BKC (0.01-0.05%) 3.Tonicity adjusting material- to adjust tonicity of nasal drops • E.g. sodium chloride, dextrose 4. Buffer- to adjust the pH of product • E.g. phosphate buffer pH 6.5. 5. Medicament- • Ephedrine hydrochloride, corticosteroid etc

Method of preparations • Simple solution method if required heating can be done